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Filed: July 14, 2003

### **REMARKS**

Claims 1 - 13 are currently pending and under examination. By this amendment, claims 1 and 11 have been amended and new claims 14 - 17 have been added. Claims 1 - 13 stand rejected. Claims 1 and 11 and new claim 17 are independent. Accordingly, by this amendment claims 1 - 17 are currently pending and under examination.

Claim 1 has been amended to correct minor grammatical errors and is thus fully supported in the specification as originally filed.

Support for amended claim 11 new claim 15 may be found, *inter alia*, in the specification as originally filed at Page 9, paragraph [00070], Page 17, paragraphs [000115 - 000118] and in Figures 1, 8, 9, 10, 11 and 13, which demonstrate that the test strip is oriented below the filter.

Support for new claims 14, 16 and 17 may be found, *inter alia*, in the specification as originally filed at Page 9, paragraph [00070] and in Figures 1, 8, 9, 10, 11 and 13, which demonstrate that the test strip is secured by the filter in such a manner as to not be in contact with the interior of the test strip container when the device is assembled.

Applicants respectfully request consideration of claims 1 - 17 in light of the remarks that follow.

### **Rejection Under 35 U.S.C. 103(a)**

On page 2 of the November 30, 2005 Office Action the Examiner rejected claims 1 - 4 and 6 - 13 under 35 USC §103(a) as being unpatentable over Nason (U.S. Patent No. 5,869,003). Applicants respectfully disagree with this rejection and request reconsideration in light of the remarks set forth herein.

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The Office Action states that Nason discloses a self contained diagnostic test unit including a buffer container with an interior, buffer fluid and a weakened portion, a test strip held by securement which holds an end of the strip, a test strip container, a sample collector for holding a sample and shaped to receive the buffer container and having channeling member with a lumen, wherein when the buffer container is squeezed, a membrane is ruptured and reagent mixes with the sample from the lumen to the wick to the test strip.

The Office Action further states on pages 4 and 5 of the November 30, 2005 Office Action that the limitation of claim 1, "filter having a securement" and a test strip "having an end held by a securement" are met by the securement 56 of Nason. Applicants respectfully maintain that the securement 56 of Nason is structurally and functionally distinct from the claimed invention. The strip holder 56 of Nason is not part of Nason's transfer wick 82, 182 or 282, but is a separate part which "includes an elongated support arm 58 having an elongated open channel 60 for receiving and supporting the elongated porous diagnostic strip 20" (Column 6, lines 51-56 and Figure 2). Further, the diagnostic strip 20 is slide-fit positioned in the internal track defined by internal ribs 73 (Column 7, lines 12-16 and Figure 3). There is no such structure in the claimed invention nor does Nason teach a filter with a securement which holds an end of the test strip.

In contrast, as Figures 1, 8-11 and 13 of the subject application demonstrate, the test strip is secured by the securement of the filter at one end thereby allowing the remaining portion of the strip to remain out of contact with the sides of the test strip receptacle and below the filter when the device is upright. This structure and correlation permits the sample and reagents to flow over the surface of the test strip to maximize fluid transfer to the test strip without having to solely rely on wicking of the fluid by the test strip as is the case in Nason. The structure of the

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device in Nason requires that the fluid containing the sample and the reagent be wicked up the test strip. See Nason, Column 5, lines 25-27 and Figures 4, 12 and 16. Thus, the structure of the claimed invention allows for good consistent fluid transfer. See Page 8, Paragraph [00060] of the specification.

Nason does not teach or suggest that the "wick" be used to secure anything, it merely contacts the test strip to transfer fluid via wick action, but only at a single rotation position of the wick and its rotatable plug 76 which carries the wick (Column 5, lines 25-27). None of the embodiments of Nason demonstrate that the wick is in constant contact with the test strip. In all but one embodiment the wick is rotated into position in order to achieve contact with the test strip (Column 7, lines 44-51 and Column 8, lines 60-66). In the final embodiment the wick is does not contact the test strip at all (Column 9, line 58 through Column 10, line 3). In addition, the elongated support arm 58 of the strip holder 56 does not secure the strip on one end, as the filter securement of the claimed invention. The strip actually lies within the elongated open channel 60 and is thus merely enclosed in the space provided by the open channel. The wick, which comes in contact with the test strip, does nothing to secure the test strip. Fluid transfer relies on the wicking capability of the test strip to move the fluids to positions in registration with window 28. In contrast, in the claimed device, the test strip is held in place by the securement of the filter to permit fluid transfer to the surface of the test strip.

Accordingly, it would not have been obvious to use the securement (strip holder) of Nason as the filter securement in the present invention because the test strip would not have been positioned to allow for optimal fluid transfer, which would adversely affect the function of the claimed device.

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Accordingly, Applicants respectfully submit that the invention is not rendered obvious by Nason and request that the Examiner reconsider and withdraw the rejection of claims 1-4 and 6-13 under 35 U.S.C. 103(a).

On page 3 of the November 30, 2005 Office Action the Examiner rejected claim 5 under 35 USC §103(a) as being unpatentable over Nason in view of Weiler et al (U.S. Patent No. 5,131,856 ("Weiler")). The Office Action states that Weiler discloses a dispensing vial with a bulb in the form of a bellows-type cylinder upon which there is placed a longitudinal compressive force.

The deficiencies discussed above are not cured by the inclusion of Weiler because Weiler, alone or in combination with Nason, does not discuss, suggest or teach the device of claim 1. Therefore, the 35 U.S.C. 103(a) rejections of dependent claim 5 should be withdrawn and a Notice of Allowance should be issued.

#### New Claims 14 - 17

New dependent claim 14 recites:

The method of claim 11, further comprising positioning the test strip in a test strip container such that the test strip is not in contact with the sides of the container when the container is positioned in an upright manner.

New dependent claim 16 recites:

The sample testing device of claim 1, wherein said test strip is held by the securement so as not to be in contact with sides of said receptacle when the testing device is positioned in an upright manner.

Similarly, new independent claim 17 recites:

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the test strip being held by the securement so as not to be in contact with sides of said receptacle when the testing device is positioned in an upright manner.

Applicants respectfully submit that the cited references fail to teach or suggest this limitation for at least the reasons noted above. Specifically, the references do not teach or suggest a test strip being held by a securement so as to not be in contact with sides of a test strip receptacle when the testing device is positioned in an upright manner. Accordingly, claims 14, 16 and 17 are in condition for allowance.

New dependent claim 15 recites:

The sample testing device of claim 1, wherein said test strip is oriented substantially below said filter when the device is positioned in an upright manner.

Similarly, the amendment to claim 11 recites:

positioning the sample container above a filter, the filter having a test strip secured thereto below;

causing the buffer fluid to flow downward from the buffer container over the sample and through the filter ~~to~~ over the test strip.

Applicants respectfully submit that the cited references fail to teach or suggest this limitation for at least the reasons noted above. Specifically, the references do not teach or suggest a test strip oriented substantially below a filter when the device is positioned in an upright manner, such that the fluid would flow over the test strip. Accordingly, amended claim 11 and new claim 15 are in condition for allowance.

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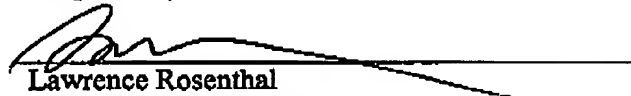
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### CONCLUSION

Applicants respectfully submit that this application is in condition for allowance. Early and favorable action is earnestly solicited. No fee is believed due in connection with the filing of this Amendment except for the \$395 fee associated with the filing of the Request for Continued Application under 37 CFR 1.114. However, if any additional fees are due the amount of such fee may be charged to Deposit Account No. 19-4709.

Applicants respectfully request a personal interview with the Examiner to discuss the arguments presented herein.

Respectfully submitted,



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